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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	19

DATE MAILED: 09/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/508,821	ROULEAU ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,9-11 and 13-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9-11 and 13-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *May 26, 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Claims 1-5, 9-11 and newly added Claims 13-25 in Paper No. 15 is acknowledged.

Priority

2. This application is a National Stage application of PCT/CA98/00884, filed September 18, 1998.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

3. The application also claims priority to CANDA 2,216,057, filed September 19, 1997. The Canadian document does not teaches the sequence of (CAR)2(CAG)nCAA as essential to the hGT1 sequence. Moreover, the document does not appear to teach SEQ ID NO: 2, 5 or 6. Therefore, the instant claims do not receive benefit of the September 19, 1997 filing date.

Specification

4. The drawings are objected because they do not contain a SEQ ID NO: either in the description of the drawings nor on the figure. Appropriate correction is required.

5. The specification refers to Figures 4A-4C, on page 4, line 13, and page 9, lines 32-33, however the sequence appear to be 4A-4E. It is unclear whether the sequence was intended to recite only three of the panels or intended to recite all of Figure 4.

6. The brief description of the drawings to does not refer to each of the drawings. For example, Figure 1 is composed of A-C. Thus, description of each of these panels is required. The brief description of the drawings refers to Figures 4A-4C, however there are "E" panels of Figure 4. Appropriate correction is required.

Information Disclosure Statement

7. The references cited in the Search Report have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office action.

New Matter

8. The amendment filed December 1, 2001 and November 9, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35

U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. Moreover, the amendments and comments provided in the response filed June 28, 2002 have been considered, but do not overcome the instant rejection.

Applicants have amended the Sequence listing to include new SEQ ID NO: 6-10. Applicants submit that the substitute sequence listing is provided to show the hGT1 amino acid sequence. "The pertinent portion of SEQ ID NO: 5 has been translated. Support for the translation of SEQ ID NO: 5 can be found in the specification at page 8, lines 30-32, describing the 5535 bp open reading frame. Support can also be found at page 8, lines 35 to page 9, line 2, describing the 490 bp intro preceding the ORF".

The specification the GT1 sequence includes a 5535 bp open-reading frame (ORF) of 5535 bps without interruption (page 8, lines 30-32). The specification teaches that the ORF is preceded by a 490 bp intron (including a consensus splice acceptor) and 19 bps of 5'UTR. The entire ORF may be coded for by a single exon (we are still missing the sequences coding for the last 12 amino acids (36 bp)) (page 9, lines 2-4).

While SEQ ID NO: 5 has been supported by the original disclosure, it appears as though the introduction of the protein sequence is not supported by the original disclosure. Based upon the text of the specification, it appears as though there are 490 bp plus 19 bps prior to the ORF, such that there are 509 bps prior to the translation start site. The amendment which has added the protein sequence appears to begin at nucleotide position 490. Therefore, there is neither a 490 bp intron preceding the ORF nor the 490 bp intron and 19 bps of the 5'UTR. Thus, insertion of a start site at position

490 does not appear to be supported by the original disclosure. The response filed June 28, 2002, page 5, attempts to explain the confusion and asserts that the translation of the nucleic acid in SEQ ID NO: 5 is not new matter since the translation was intrinsic to the sequence as originally filed. The response also states that a total of 490 bps including a 19 bps exon in the 5'UTR are upstream of the initiator codon. This also has not been supported since, the initiator occurs at 490, not with 490 prior to the start codon. Moreover, in the event that applicant finds support for the amendment, the specification requires clarification.

Furthermore, as provided in the brief description of the drawings, Figure 4 illustrates the nucleotide sequence of hGT1, wherein the upstream intron is in lowercase; human gene sequence (exon) is in upper case; and the transcription start site ATG in bold. The examiner does not see a bolded start site. The response filed June 28, 2002 submits that the oversight was a clerical error and submits a copy of the sequence provided by the inventor which was used to prepare the priority application, which shows the ATG at 490 is bold and the initator. While the examiner notes the provided sequence contains a bold ATG site. This however does not correct the application such that an ATG site in Figure 4 is in bold.

Moreover, SEQ ID NO: 5 contains numerous three letter 'tga' sites (stop codons) in the "coding sequence". This is indicative that this is not a coding region. SEQ ID NO: 6-10 are fragments from the start to stop sites, which are not supported by the original disclosure nor the original figures. The response filed June 28, 2002 agrees with the examiner that as presently translated, the amino acid sequence encoded by SEQ ID

NO: 5 is truncated at amino acid 1755 such that numerous amino acids are missing from the C-terminus. Moreover, applicants argue that if a +1 frameshift is at 1755 of SEQ ID NO: 5, the ORF continues until 6022. However, this +1 frameshift is not supported by the instant specification.

Applicant's response states that "as of the filing of this response, the discrepancy in SEQ ID NO: 5 and the statement that 'TG1 includes 5535 bps open-reading frame (OFR) of 5535 bps with out interruption' is no understood". The examiner requests clarification of this discrepancy.

Moreover, the response has made no effort to explain SEQ ID NO: 7-10 and their support in the specification. SEQ ID NO: 7-10 appear to be the smaller fragments of the protein between the stop codons which are not supported by the instant specification.

Applicant is reminded that no new matter may be entered by amendment. Applicant is required to cancel the new matter in the reply to this Office Action.

New Matter

9. Claims 19-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to "nucleic acid sequences comprising a sequence encoding the amino acid sequence as set forth in SEQ ID NO: 6" are included. However, the specification does not describe or discuses "nucleic acid

sequences comprising a sequence encoding the amino acid sequence as set forth in SEQ ID NO: 6". The specification originally provided a single nucleotide sequence. By amendment, applicants are asserting that the protein translation is defined in the specification and supported. However, there is no indication that at the time of filing, the applicant's regarded their invention as nucleic acids encoding an amino acid sequence of SEQ ID NO: 6. The concept of "nucleic acid sequences comprising a sequence encoding the amino acid sequence as set forth in SEQ ID NO: 6" does not appear to be part of the originally filed invention. Therefore, "nucleic acid sequences comprising a sequence encoding the amino acid sequence as set forth in SEQ ID NO: 6" constitutes new matter.

Moreover, the specification does not appear to teach vectors and cells comprising the SEQ ID NO: 2, 5 or the gene of Claim 1 or cells comprising the vectors. The concept of "vectors and "cells" do not appear to be part of the originally filed disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-5, 9-11, 13-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated human hGT1 gene comprising a transcribed polymorphic CAG repeat having the sequence (CAR)2(CAG)n(CAA) wherein R is A or G and n is from 7-12, wherein allelic variants of said CAG repeat are associated with a disorder and wherein n being equal to 11 is the most common allele of the hGT1 gene.

The specification describes a nucleic acid, SEQ ID NO: 5, which is 6022 nucleotides in length. The specification the GT1 sequence includes a 5535 bp open-reading frame (ORF) of 5535 bps without interruption (page 8, lines 30-32). The specification teaches that the ORF is preceded by a 490 bp intron (including a consensus splice acceptor) and 19 bps of 5'UTR. The response asserts that "the entire ORF may be coded for by a single exon (we are still missing the sequences coding for the last 12 amino acids (36 bp)) (page 9, lines 2-4).

The art teaches the genomic structure of RAI1 (Seranski et al. Gene, Vol. 270, No. 1-2, pages 69-76, 2001). The RAI1 gene for retinoid-acid induced protein 1 contains approximately 10200 nucleotides. Genbank Accession Number AJ271791 depicts the nucleic acid and provides the intron/exon structure of the nucleic acid. Exons 1-7 are depicted. The nucleic acid of RAI1 is 98% identical with SEQ ID NO: 5 over the entire length and a local similarity of 99.6% (see attached alignment). Therefore, provided that the RAI1 gene and the instant hGT1 gene are the same gene, it does not appear that at the time of filing applicant was in possession of either the full cDNA nor a gene with introns, and regulatory sequences.

Much like Example 6 and 7 in the Written Description Guidelines, the instant specification teaches a fragment of the coding sequence, namely SEQ ID NO: 5. The specification admits that the sequences coding for the last 12 amino acids are missing. Therefore, the coding sequence is a partial coding sequence. Therefore, claims directed to the human gene, for example, Claims 1, 15-16, have not been adequately described. There is no actual reduction to practice of the claimed invention, clear depiction of the claimed invention in the drawings or complete detailed description of the structure. There is a disclosure of the partial structure, namely SEQ ID NO: 7-12, however, there is no known or disclosed correlation between this function and structure of the non-described regulatory elements and the untranslated regions of the gene. The present claim encompasses full-length genes and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO: 7-12 is only a fragment of any full-length gene or cDNA species. One skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of genes which comprise SEQ ID NO: 5. Furthermore, the claims are directed to any gene comprising (CAR)2(CAG)nCAA wherein R is A or G and n is from 7-12. This is only a partial structure which does not clearly define the genus of genes which comprise the partial structure.

With respect to the claims directed to SEQ ID NO: 5, the claims lack description because SEQ ID NO: 5 is a partial cDNA also which is missing nucleotide bases as admitted in the specification. SEQ ID NO: 2 appears to contain 13CAG followed by

CAA. This sequence is not the full cDNA, therefore, a claim directed to the gene or comprising has not been described. The regulatory regions, the introns (if any) and the untranslated regions have not been described.

Furthermore, it is unclear that SEQ ID NO: 5 is a coding sequence which codes for an amino acid sequence. As provided above, and in the response filed June 28, 2002, the translation of SEQ ID NO: 5 contains three stop codons in the middle of the SEQ ID NO: 5. Therefore, it is unclear that SEQ ID NO: 5 as written is a sequence which encodes a single amino acid sequence. With respect to Claim 19 which is directed to any nucleic acid sequence comprising a sequence encoding the amino acid sequence as set forth in SEQ ID NO: 6, the specification does not describe such sequences.

Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-5, 9-11, 13-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for short CAG repeat allelic variants of hGT1 associated with schizophrenia, does not reasonably provide enablement for any allelic variants of hGT1 associated with any disorder such as psychiatric diseases, affective disorders, neurodevelopment brain disease and phenotypic variability with response to long term response to neuroleptic medication. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to an isolated human hGT1 gene comprising a transcribed polymorphic CAG repeat having the sequence (CAR)2(CAG)n(CAA) wherein R is A or G and n is from 7-12, wherein allelic variants of said CAG repeat are associated with a disorder and wherein n being equal to 11 is the most common allele of the hGT1 gene.

The specification describes a nucleic acid, SEQ ID NO: 5, which is 6022 nucleotides in length. The specification the GT1 sequence includes a 5535 bp open-reading frame (ORF) of 5535 bps without interruption (page 8, lines 30-32). The specification teaches that the ORF is preceded by a 490 bp intron (including a consensus splice acceptor) and 19 bps of 5'UTR. The response asserts that "the entire ORF may be coded for by a single exon (we are still missing the sequences coding for the last 12 amino acids (36 bp)) (page 9, lines 2-4). The specification teaches that short CAG repeat allelic variants of the hGT1 gene were associated with schizophrenia irrespective of neuroleptic response (p=0.005) (page 8, lines 17-19). The association was shown to be highly significant in Rs (p=0.0009) and marginally in NRs (p=0.12) (page 8, lines 19-20). The specification classified the alleles into long and short alleles (page 17, lines 32-34). As seen in Table 3 (page 18), a summary of the analysis in the schizophrenic patients is provided. The specification teaches that the "longer the size, the worse and poorer is the outcome" (page 19, lines 24-26).

The art teaches the genomic structure of RAI1 (Seranski et al. Gene, Vol. 270, No. 1-2, pages 69-76, 2001). The RAI1 gene for retinoid-acid induced protein 1

contains approximately 10200 nucleotides. Genbank Accession Number AJ271791 depicts the nucleic acid and provides the intron/exon structure of the nucleic acid. Exons 1-7 are depicted. The nucleic acid of RAI1 is 98% identical with SEQ ID NO: 5 over the entire length and a local similarity of 99.6% (see attached alignment). Therefore, provided that the RAI1 gene and the instant hGT1 gene are the same gene, it does not appear that at the time of filing applicant was in possession of either the full cDNA nor a gene with introns, and regulatory sequences.

Moreover, the art teaches the length of the CAG repeat in the RAI1 gene modifies the age of onset of SCA2 (abstract)(Figueroa et al. Arch Neurol. Vol. 58, No. 10, pages 1649-1653, October 2001; Hayes et al. Hum. Mol. Genetics Vol. 9, No. 12, pages 1753-1758, 2000).

Based upon the specification, it is unclear how the short alleles and long alleles correspond to number of CAG repeats, to n=7-12 and to SEQ ID NO: 12-17. The specification teaches that PCR amplified fragments range from 171-183 nucleotides. The number of CAG repeats range from 11-15. And the specification has designated these –3 to 1 (page 4). The specification teaches the most common allele is 180 bp or 14 CAG repeats is taken as 0. However based upon the claim language, SEQ ID NO: 16 is the most common allele with n=11 wherein n is the CAG repeats. Therefore, it is unclear whether the common allele has 11 or 14 CAG repeats. The analysis in the specification appear to group n=11 into the long alleles for analysis purposes. Therefore, it is unclear whether n=11 is a control or whether n=11 is also associated with schizophrenia. Based upon the specification and the claim 1, it appears as though

n=11 was associated with severe schizophrenia. However based upon Claim 13, it does not appear that applicants are claiming an association between n=11 and schizophrenia. The specification does not appear to indicate that n=7 corresponds to either shorter or longer alleles. The specification appears to place n=11, the common allele within the analysis of longer alleles (page 5, lines 30-31). Applicant's may with to use SEQ ID NO:s rather than allele numbers or n= to ensure clarity.

Thus neither the specification nor the art teach the skilled artisan how to use the invention as broadly as claimed. The specification has not provided analysis of any psychiatric disease, affective disorders, neurodevelopmental brain diseases and phenotypic variability with respect to long term response to neuroleptic medication. The specification does not provide any analysis of the association of the instant nucleic acids with the listed disorders. The specification has not provided any analysis of affective disorders, including manic depression. The genus of diseases within psychiatric disease, affective disorders, neurodevelopmental brain diseases and phenotypic variability with respect to long term response to neuroleptic medication is a very diverse set of diseases or disorders. Affective disorders are defined as a class of mental disorder's characterized by a disturbance in mood. The class of affective disorders includes manic depression, seasonal affective disorder, biopolar, for example. Each of these disorders is not well understood and does not appear to have a common pathway or mode of action. Therefore, absent guidance in the specification, it is not predictable that all affective disorders function in the same manner such that it would be expectable that association of a gene variant with a single disorder would be indicative

of association with the whole class of disorders. Similarly, psychiatric disorders is a diverse class of diseases which includes for example, Psychotic Disorders (Schizophrenia and Other Psychotic Disorders), Mood Disorders (Depressive and Bipolar), Anxiety Disorders, Substance Abuse Disorders, Personality Disorders, Somatoform Disorders, Eating, Sleeping & Impulse Control Disorders. It is unpredictable as to whether any quantity of experimentation would allow one to practice the claimed invention.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-5, 9-11, 13-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-5, 9-11, 13-25 are indefinite because the designation hGT1 is arbitrary. The instantly disclosed nucleic acid could be identified by some other arbitrary name, such as rai1 or gsgti, or the name hGT1 could be arbitrarily used to designate another nucleic acid. This rejection may be overcome by providing descriptive characterization of the claimed polypeptide.

B) Claims 1-5, 9-11, 13-25 are indefinite because it is unclear whether applicant is claiming a nucleic acid sequence which is normal or whether applicant is claiming variants of the normal which are associated with a disease. The claim requires a

nucleic acid comprising a CAG repeat having the sequence provided wherein alleleic variants are associated with a disorder and wherein n being equal to 11 is the most common allele. It is unclear whether the claim is, therefore, limited n equal to 11. The metes and bounds of the claimed invention are unclear.

C) Claims 3-4 are indefinite over the recitation "shorter than allele 0, which corresponds to n=11" because it is unclear whether the claim encompasses alleles shorter than allele 0 or rather are directed to alleles shorter than allele 0 which are n=11. Therefore, it is unclear the metes and bounds of the claims.

D) The term "less severe schizophrenia" in claim 3 is a relative term which renders the claim indefinite. The term "less severe" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification provides different categories of severity of schizophrenia, Figure 2, however, it is unclear which of these categories is deemed "less severe".

E) Claims 4-5, 9 are indefinite over the recitation "are indicative of a neuroleptic response" because it is unclear based upon the claim and the specification what is encompassed by a neuroleptic response. It is unclear whether there is a positive response, no response, intermediate response, adverse response or another type of undisclosed response.

F) Claim 9 is indefinite because claims do not recite a positive process step which clearly relates back to the preamble. The preamble states that the method is for categorizing a psychiatric patient but the final process step is directed to provide

analysis and determinination that variants shorter than allele 0 are indicative of a neuroleptic response. Therefore the claims are unclear as to whether the method is a method of categorizing patients or determining the neuroleptic response.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 1-2, 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Neri et al. (WO 97/30178, August 21, 1997).

It is noted that the intended use of the allelic variants for does not carry patentable weight in the product claim. It is noted that Neri teaches a human nucleic acid comprising CAG20CAA. Therefore, the structural limitations of the claim have been met and the product is anticipated.

Neri et al teaches transcribed DNA sequence with a high level of CAG repeat codons which are useful in diagnosing trinucleotide repeat diseases. SEQ ID NO: 19 of Neri teaches a nucleic acid from chromosome 3p14 which comprises (has) CAG20CAA

(see page 22, line 2 of sequence listing). Therefore, Neri teaches an isolated nucleic acid having the sequence of SEQ ID NO: 12-17. Since Neri has taught all of the limitations of the claims, Neri anticipates the claimed invention.

Conclusion

14. No claims allowable.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Pauline Farrier, whose telephone number is (703) 305-3550.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
September 9, 2002

W. Gary Jones
Supervisory Patent Examiner
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